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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,559	06/04/2001	Brian Allen Moser	342312001600	7874

7590 07/23/2003

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EXAMINER	
MOHAMED, ABDEL A	

ART UNIT	PAPER NUMBER
1653	7

DATE MAILED: 07/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/763,559	MOSER ET AL.	
	Examiner	Art Unit	
	Abdel A. Mohamed	1653	

-- The MAILING DATE f this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 October 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

ACKNOWLEDGMENT FOR PRIORITY, PRELIMINARY AMENDMENT, IDS, STATUS OF THE APPLICATION AND CLAIMS

1. This application is filed under 35 U.S.C. 371 on 6/4/01 having a filing date of 8/18/99 of PCT/US99/19066. Acknowledgment is made of Applicant's claim for priority based on U.S. Provisional Application No. 60/098,267 having a filing date of 8/28/98. Receipt is acknowledged of papers submitted under 35 U.S.C. § 119, which papers have been placed of record in the file. The preliminary amendment, information disclosure statement (IDS) and Form PTO-1449 filed 6/4/01 and 10/9/01, respectively are acknowledged, entered and considered. Claims 1-22 are now present for examination.

ABSTRACT MISSING

2. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

CLAIMS REJECTION-35 U.S.C. § 102(b)

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 7-11 and 14-18 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 97/47645.

WO 97/47645 discloses on page 6, compound III and in reaction scheme I and II, a reversible cyclic peptide adduct (aza cyclohexapeptide) comprising a boric or boronic acid complexed with a cyclic peptide having 1,2-cis-diol, wherein said adduct is more water-soluble than the parent 1,2-cis-diol cyclic peptide from which it is derived and the boronic acid is selected from the group consisting of alkyboronic acid or phenylboronic acid. Thus, meeting the limitation of claims 1-3. Also, the patent discloses a similar structure as claimed in claim 4 (See compound III and claim 1 of '645 patent). On reaction scheme I and II and Example 1, the prior art clearly discloses a method for forming a reversible cyclic peptide adduct by using borane complex in an aqueous solution by adding a cyclic peptide compound having 1,2-cis-diol moiety to said aqueous solution and thereby adjusting the pH to a value sufficient to effect complexation between the boric acid and cyclic peptide. Thus, meeting the limitations of claims 7-10. Further, on page 26, first paragraph the prior art discloses the adjustment of pH of the aqueous solution, in which the pH was adjusted until the solution of the filtrate was greater than pH 5, and as such meets the limitation of claim 11. On pages 4-5, the reference discloses a pharmaceutical formulation comprising a complex of a boric or boronic acid with a cyclic peptide having a 1,2-ics-diol moiety with acceptable carrier thereof, and as such meet the limitations of claims 14-18.

Therefore, WO 97/47645 discloses cyclohexapeptide compounds and a method for forming a reversible cyclic peptide adduct, comprising adding a 1,2-cis-diol cyclic peptide to an aqueous solution of a boric or boronic acid by adjusting the pH of the solution to a value sufficient for complexation and a pharmaceutical formulation thereof.

Thus, the prior art discloses the invention substantially as claimed, and as such anticipates claims 1-4, 7-11 and 14-18 as drafted.

CLAIMS REJECTION-35 U.S.C. § 103(a)

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jamison et al., (The Journal of Antibiotics, Vol. 51, No. 2, pp. 239-242, 1998) taken with Balkovec et al., (U.S. Patent No. 5,378,804) and WO 97/47645.

The reference of Jamison et al., discloses on Figure 1, the use of a reversible cyclic peptide adduct having the structure of aminophenyl group. On pages 240-241, the reference discloses the isolation, purification and *in vitro* and *in vivo* testing of the product for antifungal activity comprising adding a 1,2-cis-diol cyclic peptide to an aqueous solution of a boric or boronic acid by adjusting the pH of the solution at about 7 pH to a value sufficient for complexation of the cyclic peptide adduct. The primary reference of Jamison et al., differs from claims 1-22 in not teaching the use of a pharmaceutical formulation comprising a reversible adduct having a complex of a boric or boronic acid and a cyclic peptide with a 1,2-cis-diol moiety, and a method for treating a fungal infection by administering the compound thereof. Although, the primary reference of Jamison et al., teaches *in* vitro and *in* vivo testing of the product for antifungal activity, however, the secondary reference of Balkovec et al., discloses an aza cyclohexapeptide compounds useful for as antifungal agent to treat fungal infections such as myotic infections in mammals, especially those caused by *Candida* species such as *C. albicans*, *C. tropicalis*, etc. Thus, clearly showing the administration of the compound for the treatment of fungal infections (See e.g., col. 3, lines 29-46). Also, the reference discloses the purification of the cyclic peptide using substantially the same method steps as claimed in claims 12 and 13 and the formulation of pharmaceutical composition thereof (See e.g., col. 7, lines 18 to col. 8, lines 42; and col. 13, lines 35 to col. 14, lines 45). Further, the prior art of WO 97/47645 as discussed above discloses cyclohexapeptide compounds and a method for forming a reversible cyclic peptide adduct, comprising adding a 1,2-cis-diol cyclic peptide to an aqueous solution of a boric or boronic acid by adjusting the pH of the solution to a value sufficient for complexation and a pharmaceutical formulation thereof.

Thus, it would have been obvious to one of ordinary skill in the art to incorporate the primary reference's teachings of reversible borate or boronate complexes of 1,2-cis-diol cyclic peptide adduct having the structure of aminophenyl group and their use as a means for purification, isolation, stabilization and/or water solubilization, wherein the compounds result in increasing their water solubility into the secondary references of Balkovec et al., aza cyclohexapeptide compounds useful for as antifungal agent to treat fungal infections such as myotic infections in mammals, and WO 97/47645 formulation of reversible boronate complexes of 1,2-cisdiol cyclic peptide and pharmaceutical formulation thereof.

Therefore, the combined teachings of the prior art makes obvious the use of a reversible borate or boronate complexes of 1,2-cis-diol cyclic peptides, method for forming the boronate adduct, method of purifying reversible adduct, pharmaceutical formulation of reversible adduct and method for treating infections thereof, absent of sufficient objective factual evidence or unexpected results to the contrary.

CONCLUSION WITH FUTURE CORRESPONDANCE

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abdel A. Mohamed whose telephone number is (703) 308-3966. The examiner can normally be reached on Monday through Friday from 7:30 a.m. to 5:00 p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher S.F. Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703)

308-4242 for regular communications and (703) 305-7401 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Mohamed/AAM
July 18, 2003

CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600